Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

the effect of crocin on fasting blood sugar, lipid profile, inflammatory cytokines, pro-oxidants-antioxidants balance, depression and anxiety in the patients with metabolic syndrome

Protocol summary

Summary

The purpose of this study is to evaluate the effectiveness of crocin in patients with metabolic disorders. This is a 8-week randomized and double-blind placebo controlled clinical trial. Sixty adult patients who will be diagnosed with early stage metabolic syndrome based on AHA 2009 guidelines will be randomly assigned into crocin (15 mg/BID) or control (placebo/BID) group. At the first visit for intervention study and end of treatment course, a blood sample will be drawn and the following factors will be measured; lipid profile (LDL, TG, TC, HDL level), fasting blood sugar (FBS), inflammatory cytokines, including TNF-α, VEGF, EGF, INF-γ, and IL1-α, IL1-β, IL2, IL4, IL6, IL8, IL10, MCP-I and antibody HSP27 , pro-oxidants- antioxidants balance (PAB) and genetic and novel biomarkers of cardio - vascular disorders. In addition, the effect of crocin on the depression and anxiety of the subjects will be investigated. The crocin tablets contain 15 mg crocin (active ingredient), and Lactose and Avicel (as excipients). placebo has no crocin. The tablets are administered orally twice daily for eight weeks.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013080514279N1**
Registration date: **2015-02-01, 1393/11/12**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2015-02-01, 1393/11/12

Registrant information

Name

Mojtaba Foroutan Tanha

Name of organization / entity

Medical University of Mashhad

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Research Council of Mashhad University of Medical Sciences

Expected recruitment start date

2014-04-06, 1393/01/17

Expected recruitment end date

2014-06-28, 1393/04/07

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

the effect of crocin on fasting blood sugar, lipid profile, inflammatory cytokines, pro-oxidants-antioxidants balance, depression and anxiety in the patients with metabolic syndrome

Public title

the effect of crocin on patients with metabolic syndrome

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: the desire to participate in the study;

having no previous history of angiography; having no order of emergency angiography; having 20 number anxiety; age over 18 years old;; health in the legs and hands; patients not taking the narcotic drug alcohol, ; having no previous history of mental disorder; not using anticoagulation medications; No diabetes; Do not have the risk of deep vein thrombosis. Exclusion criteria: injury or infection at the site of reflex zone therapy; anxiolytic or hypnotic drugs in the 8 hours before reflex zone therapy; condition of hemodynamic is unstable; transfer of patient to intensive care unit and cardiopulmonary resuscitation of the patient

Age
From **18 years** old

Gender
Both

Phase
1

Groups that have been masked
No information

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description

Placebo
Used

Assignment
Parallel

Other design features
The subjects who entered the trial, chose a numbered sealed envelope containing the randomized allocation to the intervention or control group. All subjects gave written informed consent before beginning the study.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
The Regional Committee for Ethics in Research, Mashhad University of Medical Sciences

Street address
Qureshi Building, Daneshagh Street

City
Mashhad

Postal code

Approval date
2013-11-02, 1392/08/11

Ethics committee reference number
920782

Health conditions studied

1

Description of health condition studied
Metabolic syndrome

ICD-10 code
E88.81

ICD-10 code description
Metabolic syndrome

Primary outcomes

1

Description
Lipid profiles

Timepoint
Before the intervention, and 8 weeks after the intervention

Method of measurement
Laboratory analysis of the blood samples taken before the intervention and 8 weeks after the commencement of the intervention

2

Description
inflammatory cytokines

Timepoint
Before the intervention, and 8 weeks after the intervention

Method of measurement
Laboratory analysis of the blood samples taken before the intervention and 8 weeks after the commencement of the intervention

3

Description
Fast blood sugar (FBS)

Timepoint
Before the intervention, and 8 weeks after the intervention

Method of measurement
Laboratory analysis of the blood samples taken before the intervention and 8 weeks after the commencement of the intervention

4

Description
pro-oxidants- antioxidants balance (PAB)

Timepoint
Before the intervention, and 8 weeks after the intervention

Method of measurement
Laboratory analysis of the blood samples taken before the intervention and 8 weeks after the commencement of the intervention

5

Description
depression and anxiety
Timepoint
Before the intervention, and 8 weeks after the intervention
Method of measurement
Analysis of the questionnaires filled before the intervention and 8 weeks after the commencement of the intervention

6

Description
Antibody HSP27
Timepoint
Before the intervention, and 8 weeks after the intervention
Method of measurement
Laboratory analysis of the blood samples taken before the intervention and 8 weeks after the commencement of the intervention

Secondary outcomes

empty

Intervention groups

1

Description
Patients in the intervention group receive 2 oral pills/day containing 15 mg of crocin for 8 consecutive weeks. Crocin is a carotenoid, which is isolated and purified from the extract of saffron.
Category
Treatment - Drugs

2

Description
Patients in the control group receive 2 oral placebo pills/day for consecutive 8 weeks. placebo has no crocin and look like the crocin tablets.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Ghaem Hospital
Full name of responsible person
Street address
Shariati Square, Ahmadabad Street
City
Mashhad

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Research Council of Mashhad University of Medical Sciences
Full name of responsible person
Mohsen Tafaghodi
Street address
School of Pharmacy, Mashhad University of Medical Sciences, Azadi Square
City
Mashhad
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Research Council of Mashhad University of Medical Sciences
Proportion provided by this source
100
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

Contact
Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Mohammad Matin Khademi
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Person responsible for scientific inquiries

Contact

Name of organization / entity
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty